09/493,353 as filed January 28, 2000; (2) a Terminal Disclaimer Under 37 C.F.R. § 1.321(c), accompanied by the appropriate statutory disclaimer fee; and (3) a Petition for Extension of Time, requesting that the time period for responding to the Office Action be extended for a period of **two** months, from **December 13, 2002** up to and including **February 13, 2003**, accompanied by the appropriate extension fee(s).

It is believed that no other fees are required for this response. However, should the USPTO determine that any additional fee is required or that any refund is owed for this application, the Commissioner is hereby authorized and requested to charge the required fee(s) and/or credit the refund(s) due to our Deposit Account No. 04-0100.

REMARKS

Claims 1-46 are pending in this application. Applicants note, with appreciation, that claims 25 and 46 have been allowed. Claims 32, 34, 36, 38, 40 and 42 are objected to, as depending from rejected base claims. However, the Office Action states that these claims would be allowed if rewritten in independent form.

The Examiner continues to reject claims 1-15, 31, 33, 35, 37, 39, 41 and 43-44 under 35 U.S.C. § 103(a) as obvious over the cited prior art. Claims 1-15 have also been rejected as unpatentable over claims 1-64 of copending U.S. patent application Serial No. 09/493,353. Each of these rejections is discussed in turn below.

APPLICANTS' INTERVIEW SUMMARY

At the outset, Applicants wish to thank Examiner Jeanine Anne Goldberg and Supervisory Patent Examiners Gary Jones, Jeff Fredman and George Elliot for the

courtesies extended to the undersigned agent during the personal interview of December 13, 2002. Applicants' attorney, Paul Fehlner, Ph.D., was also present during the interview.

During the interview, the outstanding claim rejections for obviousness under 35 U.S.C. § 103 were discussed. In particular, Applicants reiterated their arguments that the combined use of particular HCV and HIV-specific primers in a multiplex assay of the claimed invention is not obvious over the cited prior art. Applicants also explained at length how an abundance of evidence, already of record in the prosecution history of this application, established the invention's non-obviousness.

In addition, Applicants pointed out that the HCV-specific primers the primers C131F25 and C294R25, which are recited in the pending claims of this application, are also described in co-pending U.S. patent application Serial No. 09/493,353, filed on January 28, 2000 ("the '353 application"). Applicants explained that the Examiner had previously allowed claims in the '353 application directed to the use of those primers, *e.g.*, in PCR-based assays for detecting HCV. The Examiner agreed that, since these primers had been found non-obvious in the '353 application, their claimed use in the present application must also be non-obvious. However, the Examiner stipulated that evidence from the '353 application, demonstrating the unexpected results obtained using those primers, must be made of record in the instant application as well.

In the interest of advancing prosecution of this application, Applicants submit herewith a Second Declaration by Kevin M. Gorman Under 37 C.F.R. § 1.132 (hereinafter, the "Second Gorman Declaration"). The Second Gorman Declaration describes particular experiments, that are also described in the '353 application,

demonstrating that the HCV-specific primers C131F25 and C294R25 exhibit superior results in clinical assays, when compared to existing PCR assays for detecting HCV. It is respectfully submitted that submission of the Second Gorman Declaration satisfies the Examiner's stipulation that evidence from the '353 application, demonstrating the unexpected results obtained using those primers, be made of record in the instant application.

THE REJECTIONS FOR OBVIOUSNESS UNDER 35 U.S.C. § 103 SHOULD BE WITHDRAWN

As noted above, claims 1-15, 31, 33, 35, 37, 39, 41 have been rejected as obvious over prior art cited in the Office Action. During the Interview, however, the Examiner acknowledged that these rejections would be withdrawn if evidence from the copending '353 application was presented, demonstrating unexpected results for the HCV-specific primers C131F25 (SEQ ID NO:1) and C294R25 (SEQ ID NO:2).

In the interest of advancing prosecution of this application, Applicants submit herewith the aforementioned Second Gorman Declaration. The Second Gorman Declaration describes particular experiments, that are also described in the '353 application, demonstrating that the HCV-specific primers C131F25 and C294R25 exhibit superior results in clinical assays, when compared to existing PCR assays for detecting HCV. These include superior results to a prior art PCR assay, referred to in the Second Gorman Declaration as the "Roche AMPLICOR assay" that uses primers derived from the same region of the HCV genome as the particular HCV-specific primers of this invention (see, for example, ¶ 6 of the Second Gorman Declaration). For the

Examiner's convenience, a copy of the '353 application (as filed in the USPTO on January 28, 2000) is also attached to the Second Gorman Declaration, at Tab 1.

Applicants do continue to assert that the claimed multiplex assays of this application, which use a combination of HCV- and HIV-specific primers to detect both viruses *in a single assay*, are non-obvious over the cited prior art for reasons that are already of record in the prosecution history for this application, and which were discussed in detail during the Interview. However, the accompanying Second Declaration of Kevin Gorman demonstrates that the HCV-specific primers of this invention (*i.e.*, the primers C131F25 and C294R25) exhibit superior and unexpected results compared to other PCR-based assays in the prior art. Accordingly, and as acknowledged by the Examiner, claimed methods using those particular primers must themselves be novel and non-obvious, regardless of the other arguments put forward in the prosecution of this application.

For these reasons, Applicants submit that the obviousness rejections under 35 U.S.C. § 103(a) should be withdrawn.

THE NON-STATUTORY DOUBLE PATENTING REJECTION

As noted above, claims 1-15 have also been provisionally rejected under the judicially created doctrine obviousness-type double patenting as being unpatentable over claims 1-64 of the '353 application. In order to advance prosecution and expedite and allowance of this application, Applicants submit herewith a Terminal Disclaimer Under 37 C.F.R. § 1.321(c). The Terminal Disclaimer is signed by an attorney or agent of record in this application and disclaims (except as specifically provided in that

document) the terminal part of any patent issuing from this application which would extend beyond the expiration date of any patent issuing from the '353 application. The Terminal Disclaimer is also accompanied by the statutory disclaimer fee required under 37 C.F.R. § 1.20(d) and acknowledges that a patent issuing from this application shall be enforceable only so long as it and any patent issuing from the '353 application are commonly owned.

It is believed that submission of the accompanying Terminal DIsclaimer obviates the non-statutory double patenting rejection. Applicants therefore respectfully request that the rejection be withdrawn.

CONCLUSION

For the reasons stated above, Applicants believe that the Examiner's rejections of the pending claims have been overcome and that the claims are in condition for allowance. Accordingly, the withdrawal of all objections and rejections, and reconsideration of the application are respectfully requested. The Examiner is, moreover, invited to contact the undersigned representative if she believes that it may advance prosecution of this application. An allowance is earnestly sought.

Respectfully submitted,

Dated: February 5, 2003

Samuel S. Woodley

Samuel S. Woodley, Ph.D.
Reg. No. 43,287
Agent for Applicant(s)

DARBY & DARBY P.C.
Post Office Box 5257
New York, New York 10150-5257
Tel. (212) 527-7700